ant.

inspiratory flow rates in humans). 60 L/min is a good average flow rate and is what is used experimentally to mimic inspiratory flow. As measured by a spirometer, the deposition image was obtained using a gamma camera. The percentage lung deposition (relative to the nominal dose) obtained from the ten subjects is shown in Figure 5. The average lung deposition relative to the nominal dose was 59.0%.

Please replace the paragraph at page 38, lines 1 through 6 with the following paragraph.

a13

The aerodynamic particle size distributions were characterized using a multistage liquid impinger (MSLI) operated at 60 L/min. Size 2 capsules were used for the 6 mg dose and size 000 capsules were used for the 50 mg dose. Figure 6 shows the results comparing the two particle size distributions obtained for the 6 and 50 mg doses. The fine particle fraction, <6.8  $\mu$ m relative to the total dose (FPF<sub>TD</sub><6.8  $\mu$ m), for the 6 and 50 mg doses were 74.4% and 75.0%, respectively.

Amendments to the specification are indicated in the attached "Marked Up Version of Amendments" (pages i-v).

## In the Claims

Please amend Claims 1, 5-7, 20 and 24-26. Amendments to the claims are indicated in the attached "Marked Up Version of Amendments" (pages vi-vii).

914 1.

(Amended) A method of delivering a therapeutic dose of a bioactive agent to the pulmonary system, in a single, breath-activated step, comprising:

administering particles comprising a bioactive agent, from a receptacle having a mass of particles, to a subject's respiratory tract,

wherein the particles administered to the subject's respiratory tract have a tap density of less than 0.4 g/cm<sup>3</sup> and deliver at least about 50% of the mass of particles.

a15

- 5. (Amended) The method of Claim 1 wherein the receptacle has a volume of at least about 0.48 cm<sup>3</sup>.
- 6. (Amended) The method of Claim 1 wherein the receptacle has a volume of at least about 0.67 cm<sup>3</sup>.
- 7. (Amended) The method of Claim 1 wherein the receptacle has a volume of at least about 0.95 cm<sup>3</sup>.

016 SUB

20.

(Amended) A method of delivering a therapeutic dose of a bioactive agent to the pulmonary system, in a single breath, comprising:

administering particles comprising a bioactive agent, from a receptacle having a mass of particles, to a subject's respiratory tract,

wherein the particles have a tap density less than about 0.4 g/cm<sup>3</sup> and deliver at least about 10 milligrams of the bioactive agent.

- 24. (Amended) The method of Claim 20 wherein the receptacle has a volume of at least about 0.48 cm<sup>3</sup>.
- 25. (Amended) The method of Claim 20 wherein the receptacle has a volume of at least about 0.67 cm<sup>3</sup>.
- 26. (Amended) The method of Claim 20 wherein the receptacle has a volume of at least about 0.95 cm<sup>3</sup>.